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10/532,909	12/16/2005	Robert Frigg	8932-1178-999	3108

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EXAMINER
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WOODALL, NICHOLAS W

ART UNIT	PAPER NUMBER
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3733

DATE MAILED: 08/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/532,909

Applicant(s)

FRIGG ET AL.

Examiner

Nicholas Woodall

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7 and 10-17 is/are rejected.
- 7) ☒ Claim(s) 8 and 9 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 April 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All. b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>08/23/2005</u> . | 6) <input type="checkbox"/> Other: ____.  |

## **DETAILED ACTION**

### ***Claim Objections***

1. Claim 9 is objected to because of the following informalities: claim 9 states "the blocking means", the examiner believes this should be "locking means" as stated in claim 1 and will be understood as such for examination purposes. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claim 4 recites the limitation "the inside thread" in the bore of the shaft of the longitudinal bone-fixing element. There is insufficient antecedent basis for this limitation in the claim. The examiner recommends making claim 3 dependent from claim 2 to overcome this rejection.

### ***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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6. Claims 1-4, 10, 12, 15, and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lawes (U.S. Patent 5,454,813).

Regarding claims 1, Lawes discloses a device comprising an intramedullary pin (1), a sliding sleeve (12), a longitudinal bone fixing element (7), and a locking means (19). The intramedullary pin has a central axis, a front portion (4), a rear portion (proximal end), and an opening passing through the proximal end of the pin at an oblique angle (2). The sliding sleeve (12) is able to pass through the opening (2) of the intramedullary pin (1). The sleeve (12) has a front end, a rear end, a central longitudinal bore (14), an external surface, an internal surface, and a longitudinal axis. The external surface of the sleeve (12) has sections that do not have a circular cross-section. The longitudinal bone-fixing element (7) has a head portion, that includes a fixation means (8), and a shaft that is inserted coaxially into the sleeve (12). Regarding claim 2, Lawes discloses a device wherein at the end (17) of the shaft of the bone-fixing element (7) there is a bore (11) that is coaxial with the longitudinal axis. The bore (11) also includes an internal thread (18). Regarding claims 3 and 4, Lawes discloses a device wherein the locking means (19) is an adjusting screw with a thread. The threads of the adjusting screw (19) correspond to the internal threads (18) of bore (11). Regarding claim 5, Lawes discloses a device wherein the shaft of the fixing element (7) is mounted in the sleeve (12). Regarding claim 10, Lawes discloses a device wherein the opening (2) has a cross-section with partial circular arcs. Regarding claim 12, Lawes discloses a device wherein the fixation means (8) of the fixing element (7) is selected from the group consisting a screw thread, a chisel, a pin, a T-section, and a double T-section. Lawes

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discloses a screw thread (8) as the fixation means on fixing element (7). Regarding claim 15, Lawes discloses a device wherein the locking means (19) is dimensioned to act as an axial stop relative to the opening (2). The adjusting screw (19) has a head (20), which is larger than the diameter of the opening (2). Regarding claim 16, Lawes discloses a device wherein the bone-fixing element (7) is a lag screw. It is well known in the art to use lag screws as hip screw. Lawes discloses the invention as claimed except for the internal surface of the sleeve having a circular cross-section (claim 1). It would have been an obvious matter of design choice to one skilled in the art at the time the invention was made to construct the inner surface of the sleeve of Lawes with a circular cross-section, since applicant has not disclosed that such solve any stated problem or is anything more than one of numerous shapes or configurations a person ordinary skill in the art would find obvious for the purpose of providing the inner surface of the sleeve with a circular cross-section. In re Dailey and Eilers, 149 USPQ 47 (1966).

7. Claims 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lawes (U.S. Patent 5,454,813) in view of Bramlet (U.S. Patent 6,648,889).

Regarding claim 7, Lawes discloses a device wherein the rear end of the sleeve (12) protrudes from the end of the screw (7). Lawes discloses the claimed invention except for the bone fixing element (7) having a first annular groove and the internal surface of the sleeve (12) has a second annular groove, which are engaged by a ring element. Bramlet teaches a device that includes a nail element with a bore (1) and a locking element (2) with annular grooves (14 and 34/35), which are engaged by a ring element (7) in order to detent the axial movement of the locking element in the bore of

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the nail element (2; column 8 lines 32-53). It would have been obvious to one having ordinary skill in the art at the time the invention was made to manufacture the sleeve and bone fixing element of Lawes with annular grooves and a ring element in view of Bramlet in order to detent the axial movement of the bone fixing element in the sleeve.

8. Claims 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lawes (U.S. Patent 5,454,813) in view of Frigg (U.S. Patent 6,187,007).

Lawes discloses the invention as claimed except for the head portion of the bone fixing element has a multi-start thread (claim 13) and the thread of the head portion has a thread pitch of at least 50 mm (claim 14). Frigg teaches a bone fixing element that comprises a multi-start thread and a thread pitch of at least 50 mm in order to prohibit penetration of the femur head (column 1 lines 63-65) and to not allow any torque to be transferred to the femur head (column 2 lines 4-7). It would have been obvious to one having ordinary skill in the art at the time the invention was made to manufacture the bone fixing element of Lawes with a multi-start thread and a pitch thread of at least 50 mm in order to prohibit penetration of the femur head and to not allow any torque to be transferred to the femur head.

9. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lawes (U.S. Patent 5,454,813) in view Bresina (U.S. Patent 5,908,422).

Lawes discloses the invention as claimed except for the fixing means of the bone fixing element is a helical blade. Bresina discloses an implant that comprises a fixing means that are helical blades in order to minimize the tendency to cut through the

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cancellous bone tissue after implantation and provide the required stiffness to maintain the relative orientation of the bone fragments (column 2 lines 15-19).

10. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lawes (U.S. Patent 5,454,813) in view of DeMoss (U.S. Publication 2004/0044345).

Lawes discloses the invention as claimed except for the bone fixing element being a helical screw. Demoss teaches of a helical screw that has expanding helical threads in order to create original bone to screw contact page 4 paragraph 43). It would have been obvious to one having ordinary skill in the art at the time the invention was made to manufacture the device of Lawes with a bone fixation element comprising expanding helical screws in order to create original bone to screw contact.

***Allowable Subject Matter***

11. Claims 8 and 9 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Conclusion***

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See PTO-892 for cited references the examiner felt were relevant to the application.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nicholas Woodall whose telephone number is 571-272-5204. The examiner can normally be reached on Monday to Friday 8:00 to 5:30 EST..

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NWW



EDUARDO C. ROBERT  
SUPERVISORY PATENT EXAMINER